

DETAILED ACTION

1. This Office Action is in response to applicants Response to the Restriction Requirement filed December 22, 2009. Claims 1-42 are pending in this application with claims 10-26, 36 and 42 being withdrawn from consideration; thus, claims 1-9, 27-35 and 37-41 have been treated on the merits.

Election/Restrictions

2. Applicant's election with traverse of Group 1, claims 1-41 and Species I, (Figures 1-10 & 21-24) in the reply filed on December 22, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 10-26, 36 and 42 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 22, 2009.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6, 8-9, 27-28, 37-41 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Lockhart et al. (6,643,152).

Lockhart discloses a delivery device (figures 3-4 & 6-7) actuatable (capable of being actuated) to deliver [a] substance, comprising: a delivery outlet (50) from which [the] substance is in use delivered; a gas chamber (inside 52) containing a gas (col. 6, lines 57-66) and being of reducible volume (compare figures 3 & 6 to 4 & 7, respectively), wherein a reduction in the volume of the gas chamber (inside 52) to a predetermined (amount to cause piercing of 34 and 32 to burst) volume acts to pressurize the contained gas to a predetermined pressure (amount to cause 34 to be pierced and 32 to burst); a seal element (34 and 32) disposed between the gas chamber (inside 52) and the delivery outlet (50); and an opening mechanism (compression of actuation member 52 in combination with piercing end 62 as described in col. 5, lines 30-65) configured, on reduction of the volume of the gas chamber (inside 52) to a predetermined volume (amount to cause piercing of 34 and 32 to burst), to open the seal element (34 and 32), whereupon a gas flow from the gas chamber (inside 52) acts to deliver substance from the delivery outlet (50).

Regarding claim 2, Lockhart discloses the gas chamber (inside 52) is defined in part by a flexible member (52 is flexible as shown by comparing figures 3 & 6 to 4 & 7, respectively) to which an actuating force is in use applied in actuating the delivery device (compare figures 3 & 6 to 4 & 7, respectively), with the actuating force acting to depress the flexible member (52) such as to reduce the volume of the gas chamber (gas volume is reduced by pressure) and pressurize the gas contained therein (prior to 32 bursting).

Regarding claim 3, Lockhart discloses two outwardly projecting dome shaped members that together comprise a spherical shaped outwardly-projecting (from the central axis formed by (40 & 42) member which is depressed (compare figures 3 & 6 to 4 & 7, respectively) on application of an actuating force (force used to compress 52 to pierce 34 and burst 32).

Regarding claim 4, Lockhart discloses that on each side of (40) the flexible member (52) comprises a dome-shaped member (best seen in figure 2).

Regarding claim 5, Lockhart discloses the flexible member (52) that is configured (sized and shaped) such as to provide for deflection thereof (compare figures 3 & 6 to 4 & 7, respectively), in a controlled, predetermined fashion in depressing the same (52) on application of an actuating force (force used to compress 52 to pierce 34 and burst 32).

Regarding claim 6, the flexible member (52) disclosed by Lockhart is sized and shaped to provide for controlled deflection (compare figures 3 & 6 to 4 & 7, respectively).

Regarding claim 8, the seal element disclosed by Lockhart comprises a rupturable element (54) and the opening mechanism (compression of actuation member 52 in combination with piercing end 62 as described in col. 5, lines 30-65) includes a rupturing element (54) which acts to rupture the rupturable element (34) on depression of the flexible member (52) to a predetermined extent.

Regarding claim 9, Lockhart discloses a device with the rupturing element (54) is supported (upon application of force to 52 the inner surface of 52 supports 54) at an inner surface of the flexible member (52) in opposed relation to the rupturable element

such as to be moved (when 52 is compressed 54 is compressed and 62 pierces 34) in a direction of an actuating force as applied to the flexible member (52).

Regarding claim 27, Lockhart teaches at least one substance chamber (20) for containing substance (70) operatively in fluid communication with the delivery outlet (upon actuation).

Regarding claim 28, Lockhart discloses a first (20) and second (inside 52 containing 78 as shown in figure 6) substance chambers, each separately containing substance components which are combined for delivery (upon actuation as shown in figure 7).

Regarding claims 37-38, Lockhart discloses a nasal and oral delivery device.
See: col. 1, lines 10-13.

Regarding claims 39-40, Lockhart discloses delivering substances in liquid and powdered form. See: col. 6, line 7 - col. 8, line 57.

Regarding claim 41, Lockhart discloses a delivery device, comprising: a gas-filled chamber (inside 52) of variable (capable of being varied) volume (which is varied upon actuation); a delivery outlet (50) coupled to the chamber (52 is coupled with 50 as shown in figures 3-4 & 6-7) and from which substance is deliverable (capable of being delivered), carried by the gas from the chamber (col. 6, line 60 - col. 7, line 4); a seal (34 and 32) between the chamber (inside 52) and the delivery outlet (50); and opening means (compression of actuation member 52 in combination with piercing end 62 as described in col. 5, lines 30-65) for opening the seal on reduction of the volume of the chamber to a predetermined volume (compare figures 3 & 6 to 4 & 7, respectively),

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to allow the gas pressurized by the reduction in the volume of the chamber to flow through the delivery outlet.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 7 and is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (6,643,152), as applied to claims 1-3 and 5-6 above, and further in view of af Ekenstam et al. (4,282,986).

Lockhart discloses all the limitations of claim 7, except the flexible member including ribs which provide for controlled deflection.

af Ekenstam teaches a device with a compressible dome shaped container and teaches that ribs may also be added to the container to add a retaining force such that a retaining force would be applied against actuating the container. See: col. 2, lines 24-27 and col. 4, lines 56-64.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the dome shaped flexible member disclosed by Lockhart, by placing ribs on the flexible member, as taught by af Ekenstam, in order to forma flexible member that would deliver a more controlled actuation based on the retaining force added to the flexible member.

8. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (6,643,152), as applied to claim 1 above, and further in view of Brunet et al., (CA 2,020,425 A1).

Lockhart discloses all the limitations of claim 29 except the device further comprising an expansion mechanism for expanding the body cavity.

First, it should be noted that if the device disclosed by Lockhart were placed in an oblong body cavity, such as a mouth, and then turned, the outer edges of the 40 & 42 would inherently provide an expansion mechanism based. However, the examiner has interpreted the expansion mechanism more narrowly based upon applicants elected Species.

Brunet teaches a device with an expansion mechanism (the tapered shape of the distal end of the device shown in figure 8) that would provide for sealing engagement (based on its tapered shape) for sealing engagement with a body cavity. See: figure 8 and paragraph bridging pages 11 & 12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device disclosed by Lockhart, by adding a tapered distal end, as taught by Brunet in order to form a device that could a more efficient delivery of medicament to the nasal passages of a wide variety of users with differently sized nasal passages.

Claim Objections

9. Claims 31-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Farris (Des. 432,647); Harrison (7,163,013); Linner (Des. 361,380); Lockhart et al. (DE 10032937); Hein (1,971,345); Hassler (Des. 177,044); Van Eck (3,989,045); Petit (5,328,099); Fuisz et al (6,6062,213); Britto et al (6,098,619); Harrison et al. (6,866,039); Rex et al. (5,542,411); Elk et al (5,683,361); Pera (5,669,378) which all discloses dispenser devices.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771